MAIL STOP APPEAL BRIEF-PATENTS
0515-1108
PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of	Appeal No. _____
GARBE, Jean-Francois	Confirm. No. 4287
Serial No. 10/530,801	Group Art Unit 3731
File January 17, 2006	Examiner Tuan Van NGUYEN

DEVICE FOR CONNECTION BETWEEN A CORPOREAL DUCT AND A PROSTHESIS

APPEAL BRIEF

MAY IT PLEASE YOUR HONORS:

(i) Real Party in Interest

The real party in interest is the present assignee, PROTOMED, of Marseille, France.

(ii) Related Appeals and Interferences

None.

(iii) Status of the Claims

Claims 1-10, 17 and 18 have been canceled, leaving claims 11-16 and 19-25 as the only claims in the case. It is from the final rejection of these claims, other than claim 23, that the present appeal is taken.

Thus, the claims on appeal are claims 11-16, 19-22, 24 and 25.

In thus declining to pursue the appeal as to claim 23, however, we do not concede the propriety of the rejection of claim 23 under 35 USC §103 as being unpatentable over WEADOCK in view of SCHULSINGER et al., and further in view of GOLDSTEEN et al. In fact, claim 22, also rejected on this same ground, is believed to be patentable over this combination of references for the reasons to be given hereinafter.

(iv) Status of Amendments

No amendment was filed subsequent to the final rejection of January 29, 2009.

(v) Summary of Claimed Subject Matter

The claimed subject matter can best be summarized by display of the three remaining independent claims, namely, claims 22, 24, and 25, with appropriate reference numerals and page and line citations being inserted therein, as follows:

22. A connecting device (14)(page 3, line 30) for connecting a body duct (12)(page 3, line 23) and a prosthesis (10)(page 3, line 23) at a first end of the prosthesis intubated in the body duct, the prosthesis having an essentially tubular shape (page 3, line 26), the connecting device comprising:

a tubular mesh (page 2, line 17) sleeve adapted to be positioned within an interior of the prosthesis proximate the first end of the prosthesis, the mesh sleeve presenting opposing sleeve ends (Figs. 5 and 6), the mesh sleeve being capable of radial expansion between a first stable minimal-diameter configuration and a second after-expansion configuration that is also stable (page 2, lines 18 and 19), the mesh sleeve including:

a plurality of transfixion pins (22)(Figs. 1A and 1B)(page 4, line 10 et seq.) positioned at substantially regular intervals (page 4, line 1) about a circumference of the mesh sleeve proximate each sleeve end, each of the transfixion pins having a pin length sufficient to pass entirely through a wall of the body duct and each of the transfixion pins being adapted to transfix a portion of the body duct and the prosthesis surrounding the mesh sleeve upon radial expansion of the mesh sleeve to the second stable configuration (page 5, lines 20-22)(Fig. 1B), wherein each of the transfixion pins have at least a bottom portion extending longitudinally in an outward and substantially perpendicular direction from an external surface of the mesh sleeve (Fig. 1A), and wherein each of the

transfixion pins have a hemostatic profile comprising a circular base section extending to a trihedral-shaped end portion (page 5, lines 2-4)(Figs. 2A and 2B) whereby hemostasis is achieved at transfixion sites formed by the transfixion pins in the wall of the body duct upon radial expansion of the mesh sleeve to the second stable configuration.

24. A connecting device adapted for end-to-end anastomosis of at least two body ducts (12-1, 12-2; 12'-1, 12'-2, 12'-3)(Figs. 5 and 6)(page 6, lines 1-14) through an intermediary prosthesis (10, 10')(Figs. 5 and 6) having at least two ends, each end being intubated in one of the at least two body ducts, the connecting device comprising:

a sleeve (14-1, 14-2; 14'-1, 14'-2, 14'-3)(Figs. 5 and 6)(page 6, lines 11-12) positioned within an interior of the prosthesis proximate each end of the prosthesis intubated in a duct end, the sleeve presenting opposing sleeve ends, the sleeve comprising:

a mesh cylinder (page 2, line 17) capable of radial expansion between a first stable minimal-diameter configuration and a second after-expansion configuration that is also stable (page 2, lines 18 and 19), and

a plurality of transfixion pins (22)(Figs. 1A and 1B)(page 4, line 10 et seq.) positioned at substantially regular intervals (page 4, line 1) about a circumference of the mesh cylinder proximate each sleeve end, each of the transfixion pins having a pin length sufficient to pass entirely through a wall of the body duct and each of the transfixion pins being adapted to transfix a portion of the body duct and the prosthesis surrounding the mesh cylinder upon radial expansion of the mesh cylinder to the second stable configuration (page 5, lines 20-22)(Fig. 1B), wherein each of the transfixion pins have at least a bottom portion extending longitudinally in an outward and substantially perpendicular direction from an external surface of the mesh cylinder (Fig. 1A), and wherein each of the transfixion pins have a hemostatic profile comprising a circular base section extending to a trihedral-shaped end portion (page 5, lines 2-4)(Figs. 2A and 2B) whereby hemostasis is achieved at transfixion sites formed by the transfixion pins in the wall of the body duct upon radial expansion of the mesh cylinder to the second stable configuration.

25. A method for positioning connecting devices adapted for end-to-end anastomosis of at least two body ducts (14-1, 14-2; 14'-1, 14'-2, 14'-3)(Figs. 5 and 6)(page 6, lines 11-14) through an intermediary prosthesis (10,10')(Figs. 5 and 6) having at least two ends, each end being intubated in one of the at least two body ducts, the method comprising:

intubating a first end of the prosthesis in a first body duct (page 5, line 29);

securing the first end of the prosthesis to the first body duct by a first connecting device, the first connecting device and an inflatable balloon catheter being introduced into an interior of the prosthesis through a second end of the prosthesis (page 5, lines 30-32), the first connecting device comprising:

a mesh sleeve (Fig. 1A) capable of radial expansion between a first stable minimal-diameter configuration and a second after-expansion configuration that is also stable, and

a plurality of transfixion pins (22)(figs. 1A and 1B)(page 4, line 10 et seq.) positioned at substantially regular intervals (page 4, line 1) about a circumference of the mesh sleeve proximate each sleeve end, each of the transfixion pins having a pin length sufficient to pass entirely

through a wall of the body duct and each of the transfixion pins being adapted to transfix a portion of the body duct and the prosthesis surrounding the mesh sleeve upon radial expansion of the mesh sleeve to the second stable configuration (page 5, lines 20-22)(Fig. 1B), wherein each of the transfixion pins have at least a bottom portion extending longitudinally in an outward and substantially perpendicular direction from an external surface of the mesh sleeve (Fig. 1A), and wherein each of the transfixion pins have a hemostatic profile comprising a circular base section extending to a trihedral-shaped end portion (page 5, lines 2-4)(Figs. 2A and 2B) whereby hemostasis is achieved at transfixion sites formed by the transfixion pins in the wall of the body duct upon radial expansion of the mesh sleeve to the second stable configuration;

intubating a second end of the prosthesis in a second body duct; and

securing a second connecting device, by a catheter introduced into the interior of the prosthesis through an orifice formed in a wall of the prosthesis that is subsequently re-closed (page 6, lines 1-4), the

second connecting device being substantially identical to the first connecting device (Figs. 5 and 6).

(vi) Grounds of Rejection to be Reviewed on Appeal

The grounds of rejection to be reviewed on appeal are as follows:

a) the rejection of claim 22 under 35 USC §103(a) as being unpatentable over WEADOCK in view of SCHULSINGER et al. and further in view of GOLDSTEEN et al.

b) the rejection of claims 11-13 and 21 under 35 USC §103(a) as being unpatentable over WEADOCK in view of SCHULSINGER et al. and GOLDSTEEN et al., and further in view of MARTIN.

c) the rejection of claims 14, 15 and 21 under 35 USC §103(a) as being unpatentable over WEADOCK in view of SCHULSINGER et al., MARTIN and GOLDSTEEN, and further in view of DEROWE et al.

d) the rejection of claim 16 as unpatentable over WEADOCK in view of SCHULSINGER, GOLDSTEEN et al., and MARTIN, or further in view of CHOBOTOV et al.

e) the rejection of claims 19 and 20 under 35 USC §103(a) as being unpatentable over WEADOCK in view of SCHULSINGER et al., GOLDSTEEN et al., MARTIN and CHOBOTOV et al., or further in view of DUHAYLONGSOD et al.

f) the rejection of claim 24 under 35 USC §103(a) as unpatentable over GOLDSTEEN et al. in view of WEADOCK and SCHULSINGER et al., and further in view of DEROWE et al.

We note that claim 25 is in the case and was presented by the amendment of November 17, 2008. However, page 1 of the final rejection does not recite claim 25, nor does the final rejection deal with claim 25 by that claim number. On the other hand, the rejection of claim 24, set forth above, speaks in terms of the method, and claim 25 is the only method claim in the case. Therefore, it may be that the Examiner was dealing with claim 25 when reciting the rejection of claim 24.

It is suggested that the Examiner's Answer deal with both claims 24 and 25; and if the rejection of one or the other is no different from a rejection already of record, there will be no need to reopen prosecution or take any other unusual step: In other words, let the appeal proceed with a simple explanation of which rejection applies to which claim.

(vii) Argument

a) The rejection of claim 22 under 35 USC §103 as being unpatentable over WEADOCK in view of SCHULSINGER et al. and further in view of GOLDSTEEN et al.

WEADOCK is relied on for disclosing an anastomotic coupler 20 which includes a tubularly shaped structure 22 consisting of cells 24 which allow for radial expansion and forming a compliant annular body. Attached to the opposite ends 24, 26 of the annular compliant body 22 are vessel or graft engaging elements, such as axially and outwardly bent staples 28 30 which are spaced around the periphery of the

body structure 22 (Figure 2 and col. 5, lines 21-36). Figure 3 illustrates the upper end portion 32 of the vascular graft 10 (or 18) with the anastomotic coupler 20 positioned thereover and having the end of the graft everted such that the staples 28 at the one end 24 of the coupler 20 pierce engagingly through the graft and the wall of the aorta 36, whereas the other staples 30 below the averted upper end portion of the graft are adapted to engage into the wall of the body vessel (Figure 3 and col. 5, lines 37-44). Figure 4 shows a delivery system and device 40 for emplacement of the graft 10. The prosthesis delivery device includes an essentially hollow tubular or cylindrical syringe-like or catheter member 41 having an axially movable handle 42 for pushing and deploying the device in the body vessel, with a rod member 43 extending towards the upper end of member 41 into engagement with the aortic anastomotic coupler 20, the staples 28 of which engage the wall of the aorta 36.

SCHULSINGER is relied on for disclosing a microsurgical needle for use in microsurgical techniques. Said needle has four specific segments:

- a distal segment that is straight with a circular cross section and has, a tip with a triangular cross section having three sharp edges for cutting rather than tearing tissue during penetration,

- a middle segment of the needle that has an acutely angled arched shape, and a transitional cross section which transitions between a squared in cross section of a main shaft segment and the circular cross section of the straight distal segment,
- a main shaft segment that is squared in cross section and that forms a broadly curved or arched shaft segment,
- a proximal end that forms a suture attachment segment and that is preferably circular in cross section (col. 1, line 65-col. 2, line 17).

GOLDSTEEN is relied on for disclosing a tubular artificial graft for attachment to a patient's tubular body tissue which has an initially radially relatively small connector structure adjacent each end of its ends. After a connector structure is properly positioned relative to the body tissue, the connector structure is radially enlarged to securely engage the tissue tube. In addition to providing mechanical attachment of the artificial graft to the body tissue tube, the radial enlargement of the connector structures provides a fluid tight seal between the graft and the body tissue tubes (col. 1, lines 29-43). Inflation of balloons may be used to radially enlarge said connector structures either by plastically deforming the connector structures or by releasing the connector structures from frangible or other similar restraints (col. 4, lines 27-30).

However, WEADOCK does not disclose a connecting device for connecting a body duct and a prosthesis at a first end of the prosthesis intubated in the body duct, the prosthesis having an essentially tubular shape, the connecting device comprising:

- a tubularly mesh sleeve adapted to be positioned within an interior of the prosthesis proximate the first end of the prosthesis, the mesh sleeve having sleeve ends, the mesh sleeve being capable of radial expansion between a first stable minimal-diameter configuration and a second after-expansion configuration that is also stable, the mesh sleeve including a plurality of transfixion pins positioned at substantially regular intervals about a circumference of the mesh sleeve proximate each end, each of the transfixion pins having of a pin length sufficient to pass entirely through a wall of the body duct, and each of the transfixion pins being adapted to transfix a portion of the body duct and the prosthesis surrounding the mesh sleeve upon radial expansion of the mesh sleeve to the second stable configuration, wherein each of the transfixion pins have at least their bottom portion extending longitudinally in an outward and substantially perpendicular direction from an external surface of the mesh sleeve, and

- wherein the transfixion pins have a hemostatic profile comprising a circular base section extending to a trihedral-shaped end portion whereby hemostasis is achieved at transfixion sites formed by the transfixion pins in the wall of the body duct upon radial expansion of the mash sleeve to the second stable configuration.

On the contrary, WEADOCK teaches the use of a tubularly shaped structure having attached to its opposite ends axially and outwardly bent staples. According to Figures 2 to 4, these staples have their bottom portion extending longitudinally in a parallel direction with the longitudinal axis of the body structure. These staples therefore do not have their bottom part extending longitudinally in an outward and substantially perpendicular direction from an external surface of the tubularly shaped structure.

Moreover, WEADOCK only teaches the use of staples and does not disclose the use of transfixion pins having a hemostatic profile comprising a circular base section extending to a trihedral-shaped end portion.

Recall that the term “hemostasis” means stopping the blood circulation and, in the present application context, stopping the bleeding. Hence the function of the profile of the transfixion pins is to stop the bleeding at transfixion sites in the wall of the body duct created by the transfixion pins.

WEADOCK fails to disclose, or even suggest, such a function that is most relevant to the present invention since the mesh sleeve must enable a tight and safe connection between a body duct and a prosthesis intubated in the body duct without any risk of post surgical bleeding.

In addition, WEADOCK fails to disclose the use of an independent device for connecting a body duct and a prosthesis at a first end of the prosthesis intubated in the body duct. It only discloses an aortic endoprosthesis and not an independent stand alone (unattached) and single connecting device as the one recited in the present invention.

Hence WEADOCK fails to disclose all the essential features of the teaching of independent claim 22 (resp. new independent claim 23) and therefore independent claim 22 (resp. new independent claims 23) is new with respect to this document.

SCHULSINGER does not disclose a connecting device for connecting a body duct and a prosthesis at a first end of the prosthesis intubated in the body duct, the prosthesis having an essentially tubular shape, the connecting device comprising a tubular mesh sleeve adapted to be positioned within an interior of the prosthesis proximate the first end of the prosthesis, the mesh sleeve having sleeve ends, the mesh sleeve being capable of radial expansion between a first stable minimal-diameter configuration and a second after-

expansion configuration that is also stable, the mesh sleeve including a plurality of transfixion pins positioned at substantially regular intervals about a circumference of the mesh sleeve proximate each sleeve end, each of the transfixion pins having a pin length sufficient to pass entirely through a wall of the body duct and each of the transfixion pins being adapted to transfix a portion of the body duct and the prosthesis surrounding the mesh sleeve upon radial expansion of the mesh sleeve to the second stable configuration, wherein each of the transfixion pins have at least their bottom portion extending longitudinally in an outward and substantially perpendicular direction from an external surface of the mesh sleeve, and wherein each of the transfixion pins have a hemostatic profile comprising a circular base section extending to a trihedral-shaped end portion whereby hemostasis is achieved at transfixion sites formed by the transfixion pins in the wall of the body duct upon radial expansion of the mesh sleeve to the second stable configuration.

SCHULSINGER is concerned only with a microsurgical suture needle providing “an easy angle, better stability, improved point placement, and better control than conventional needles, while the point serves to minimize trauma” (col.2, lines 14-17).

Said needle includes four specific segments (Col.2, line 43) (1) A distal segment of the needle that is straight

with a circular base section and with a tip having three sharp edges for culling rather than tearing tissue during penetration; (2) a middle segment of the needle that has an acutely angled arched type; (3) a main shaft segment that is generally squared in cross section and forms a broadly curved segment; (4) the proximal end of the needle that forms a suture attachment segment (col. 2, lines 1-14).

SCHULSINGER does not teach or even suggest the function of “hemostasis”.

Hence, SCHULSINGER fails to disclose the teaching of independent claim 22 (resp. new independent claims 23) and therefore independent claim 22 (resp. new independent claims 23) is new with respect to this document.

However, according to the present specification, ‘Due to the fact that the sleeve can expand within a significant range of diameters, the ratio between the final, in situ, diameter of the sleeve and the initial diameter being advantageously greater than 2, and because its final state is stable ..., the sleeve is effectively squeezed against the intubed portions in question that is both impermeable and firm thanks to the transfixion pins of said intubed portions (page 3, par. 41).

Furthermore, the capability of the sleeve to expand to varying sizes allows it, by way of a single-size sleeve, to be used for anastomoses, for example, of vessels whose

diameters may vary over an extended range, for example, arteries, with a diameter between 6 and 30 mm (page 3, par. 42)."

Hence, the problem is how to produce an independent, stand alone (unattached) and single device for connecting previously intubed ends of a body duct and a prosthesis which ensures a tight, safe and secure link of the connecting device without any risk of post surgical bleeding, and that may be used over an extended range of body duct diameters.

The Examiner fails to provide any teaching in the prior art suggesting or disclosing all the features of the present invention.

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.

As is shown hereabove, there is absolutely no teaching, suggestion or disclosure in the cited prior art that would provide a basis for the combination of the said prior art since none of the cited prior art discloses the function of "hemostasis".

The present technical solution having been formulated, one may not start from something known and show how to arrive at the present solution by a series of apparently easy steps. This is an ex post facto analysis.

The ex post facto analysis of the Examiner appears clearly since the Examiner only considers a segment of the suturing needle disclosed by SCHULSINGER, the distal segment whereas the needle has four specific segments (col.2, line 43)".

It is not permitted to consider only part of the teaching of a cited prior art unless the person skilled in the art is taught or suggested to do so. There is no basis in the teaching of WEADOCK to do so.

Moreover, SCHULSINGER discloses a microsurgical suturing needle for use in microsurgical techniques (col. 1, lines 66-67). The needle profile enables to penetrate the tissue and to cut said tissue during penetration but the needle does not remain in the tissue after penetration.

Hence, there would be no incitement to use such a profile of the suturing needle for the staples disclosed by WEADOCK.

In the present invention, the transfixion pins have a hemostatic profile comprising a circular base section extending to a trihedral-shaped end portion, whereby hemostasis is achieved at transfixion sites in the wall of the body duct created by the transfixion pins. The circular base section enables to fill the void in the tissue. The circular base section acts as a "closure" which enables the transfixion pins to ensure a tight, safe and secure link over the time.

On the contrary, the prior art would have incited the person skilled in the art to use either a suturing thread (SCHULSINGER) or a piercing element that does not present an hemostatic profile (WEADOCK) for connecting a body duct and a prosthesis at a first end of the prosthesis intubated in the body duct.

(viii) Rejections b), c), d) and e) on Rejection a), as recited above, plus respectively MARTIN or DEROWE, or CHOBOTOV et al., or DUHAYLONGSOD et al.

The application of any of these four latter references as recited above, will do nothing to overcome the fundamental defects of the combination of WEADOCK, SCHULSINGER et al. and GOLDSTEEN as pointed out under Section a) above. Therefore, it is not believed that the rejections involving any of those last four references need be discussed in detail. They all fail for the same reasons as set forth under a) above.

f) The rejection of claim 24 as unpatentable over GOLDSTEEN et al. in view of WEADOCK and further in view of SCHULSINGER et al., and still further in view of DEROWE et al.and GOLDSTEEN

As indicated above, the Examiner may have been thinking of method claim 25 when rejecting device claim 24 on this ground; but never mind that: Let's get on with the appeal.

As to the method claim, whether called claim 24 or claim 25, GOLDSTEEN fails to disclose all the steps of the claimed method for positioning connecting devices adapted for end-to-end anastomosis of at least two body ducts through an intermediary prosthesis having at least two ends, each end being intubated in one of the at least two body ducts.

GOLDSTEEN seeks to join the ends of two separated vessels with an artificial graft having a radially enlargeable connector structure at each axial end portion of its structure (col. 2, lines 45-46).

GOLDSTEEN fails to disclose the connection of at least two body ducts through an intermediary prosthesis having extremities intubed in and portions of the duets.

Moreover, “the tissue-piercing structures 36 of the connector structures 30 (see Fig. 5) which radially penetrate the adjacent body tissue structure 10 may be barbed to substantially prevent them from coming out of the tissue they have pierced” (col.3, lines 44-52).

Thus, GOLDSTEEN fails to disclose that the tissue-piercing structures 36 of the connector structures 30 have a length sufficient to pass entirely through a portion of the intubed ends of the body duct and the prosthesis.

GOLDSTEEN also fails to disclose piercing structures having a hemostatic profile comprising a circular base section extending to a trihedral-shaped end portion.

The teaching of GOLDSTEEN would have incited the person skilled in the art to prevent the tissue-piercing structures from coming out of the tissue. Thus it would not have incited the person skill in the art to achieve hemostasis at transfixion sites.

GOLDSTEEN fails to disclose the steps of intubating a first end of the prosthesis in a first body duct, securing the first end of the prosthesis to the first body duct by a first connecting device, the first connecting device and an inflatable balloon catheter being introduced into an interior of the prosthesis through a second end of the prosthesis and then intubating a second end of the prosthesis in a second body duct.

On the contrary, GOLDSTEEN teaches to first insert each axial end of the graft into the body tissue tubing (col.2, line 55-58) and then to introduce balloons initially non-inflated into apertures made in the graft. After removing the balloons, these apertures are closed by tightening and securing purse string sutures (col. 4, lines 40-45). Thus the operating times can be very long.

Thanks to the present method the number of orifices made in the prosthesis in order to introduce the catheters is reduced and the prosthesis is not weakened. Moreover, required operating times are reduced since there are less orifices to close, enabling a reduction in mortality risk.

DEROWE, on the other hand, does nothing to overcome the shortcomings of GOLDSTEEN with respect to the claimed method, as pointed out above, and so need not be discussed in greater detail at this time.

It will be apparent, therefore, that no reference of record nor any proper combination thereof, no matter how applied, renders obvious the subject matter of any of the claims on appeal.

It is accordingly respectfully requested that the final rejection be reversed as to all grounds presented on appeal.

Respectfully submitted,

YOUNG & THOMPSON

/Robert J. Patch/

Robert J. Patch, Reg. No. 17,355
209 Madison Street, Suite 500
Alexandria, VA 22314
Telephone (703) 521-2297
Telefax (703) 685-0573
(703) 979-4709

RJP/mjr/fb

September 21, 2009

(ix) Claims Appendix

1-10. (Cancelled)

11. (Previously Presented) The device according to claim 22, wherein the mesh sleeve comprises an openwork steel cylinder including diamond-shaped cutouts, the transfixion pins being attached to the cylinder at each end at a plurality of intersections of sides of the diamond- shaped cutouts.

12. (Previously Presented) The device according to claim 22, wherein an intermediate portion of the sleeve also comprises a plurality of intermediate transfixion pins.

13. (Previously Presented) The device according to claim 22, wherein, in expansion during fixation, a ratio of a final diameter of the sleeve to an initial diameter of the sleeve is greater than 2.

14. (Previously Presented) The device according to claim 12, wherein the series of transfixion pins on each end of the sleeve are straight, and wherein the intermediate transfixion pins are slightly curved and have points oriented toward one end or another end of the sleeve or randomly in any other direction.

15. (Previously Presented) The device according to claim 14, wherein the intermediate transfixion pins have an end portion inclined at an angle of between 0 degrees and 10 degrees.

16. (Previously Presented) The device according to claim 12, wherein the transfixion pins of the ends of the sleeve are of a reduced height in relation to a height of the intermediate transfixion pins.

17-18. (Cancelled)

19. (Previously Presented) The device according to claim 11, wherein the transfixion pins are attached to the cylinder by soldering.

20. (Previously Presented) The device according to claim 11, wherein the transfixion pins are attached to the cylinder by gluing.

21. (Previously Presented) The device according to claim 15, wherein the end portion of the intermediate transfixion pins is inclined at an angle of about 5 degrees.

22. (Previously Presented) A connecting device for connecting a body duct and a prosthesis at a first end of the prosthesis

intubated in the body duct, the prosthesis having an essentially tubular shape, the connecting device comprising:

a tubular mesh sleeve adapted to be positioned within an interior of the prosthesis proximate the first end of the prosthesis, the mesh sleeve presenting opposing sleeve ends, the mesh sleeve being capable of radial expansion between a first stable minimal-diameter configuration and a second after-expansion configuration that is also stable, the mesh sleeve including:

a plurality of transfixion pins positioned at substantially regular intervals about a circumference of the mesh sleeve proximate each sleeve end, each of the transfixion pins having a pin length sufficient to pass entirely through a wall of the body duct and each of the transfixion pins being adapted to transfix a portion of the body duct and the prosthesis surrounding the mesh sleeve upon radial expansion of the mesh sleeve to the second stable configuration, wherein each of the transfixion pins have at least a bottom portion extending longitudinally in an outward and substantially perpendicular direction from an external surface of the mesh sleeve, and wherein each of the transfixion pins have a hemostatic profile comprising a circular base section extending to a trihedral-shaped end portion whereby hemostasis is achieved at transfixion sites formed by the transfixion

pins in the wall of the body duct upon radial expansion of the mesh sleeve to the second stable configuration.

24. (New) A method for positioning connecting devices adapted for end-to-end anastomosis of at least two body ducts through an intermediary prosthesis having at least two ends, each end being intubated in one of the at least two body ducts, the connecting device comprising:

a sleeve positioned within an interior of the prosthesis proximate each end of the prosthesis intubated in a duct end, the sleeve presenting opposing sleeve ends, the sleeve comprising:

a mesh cylinder capable of radial expansion between a first stable minimal-diameter configuration and a second after-expansion configuration that is also stable, and

a plurality of transfixion pins positioned at substantially regular intervals about a circumference of the mesh cylinder proximate each sleeve end, each of the transfixion pins having a pin length sufficient to pass entirely through a wall of the body duct and each of the transfixion pins being adapted to transfix a portion of the body

duct and the prosthesis surrounding the mesh cylinder upon radial expansion of the mesh cylinder to the second stable configuration, wherein each of the transfixion pins have at least a bottom portion extending longitudinally in an outward and substantially perpendicular direction from an external surface of the mesh cylinder, and wherein each of the transfixion pins have a hemostatic profile comprising a circular base section extending to a trihedral-shaped end portion whereby hemostasis is achieved at transfixion sites formed by the transfixion pins in the wall of the body duct upon radial expansion of the mesh cylinder to the second stable configuration.

25. A method for positioning connecting devices adapted for end-to-end anastomosis of at least two body ducts through an intermediary prosthesis having at least two ends, each end being intubated in one of the at least two body ducts, the method comprising:

intubating a first end of the prosthesis in a first body duct;

securing the first end of the prosthesis to the first body duct by a first connecting device, the first connecting device and an inflatable balloon catheter

being introduced into an interior of the prosthesis through a second end of the prosthesis, the first connecting device comprising:

a mesh sleeve capable of radial expansion between a first stable minimal-diameter configuration and a second after-expansion configuration that is also stable, and

a plurality of transfixion pins positioned at substantially regular intervals about a circumference of the mesh sleeve proximate each sleeve end, each of the transfixion pins having a pin length sufficient to pass entirely through a wall of the body duct and each of the transfixion pins being adapted to transfix a portion of the body duct and the prosthesis surrounding the mesh sleeve upon radial expansion of the mesh sleeve to the second stable configuration, wherein each of the transfixion pins have at least a bottom portion extending longitudinally in an outward and substantially perpendicular direction from an external surface of the mesh sleeve, and wherein each of the transfixion pins have a hemostatic profile comprising a circular base section extending to a trihedral-shaped end portion whereby hemostasis is achieved at transfixion sites formed by the

transfixion pins in the wall of the body duct upon radial expansion of the mesh sleeve to the second stable configuration;

intubating a second end of the prosthesis in a second body duct; and

securing a second connecting device, by a catheter introduced into the interior of the prosthesis through an orifice formed in a wall of the prosthesis that is subsequently re-closed, the second connecting device being substantially identical to the first connecting device.

(x) Evidence Appendix.

None

(xi) Related Proceedings Appendix

None.